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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV,

*Plaintiffs*,

v.

ALKEM LABORATORIES LTD. and ASCEND LABORATORIES, LLC,

*Defendants*.

Civil Action No. _____

**COMPLAINT FOR PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPNV"), (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendants Alkem Laboratories Ltd. ("Alkem") and Ascend Laboratories, LLC ("Ascend") (collectively, "Defendants"), hereby allege as follows:

## NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 10,869,844 (the "'844 Patent"), United States Patent No. 11,173,134 (the "'134 Patent"), United States Patent No. 11,311,500 (the "'500 Patent"), and United States Patent No. 11,446,260 (the "'260 Patent").

2. This action relates to the submission of Abbreviated New Drug Application ("ANDA") No. 218468 by Defendants to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

## THE PARTIES

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. JPNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

5. On information and belief, Alkem is a corporation organized and existing under the laws of India, having a place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai 400013, Maharashtra, India.

6. On information and belief, Ascend is a corporation organized and existing under the laws of New Jersey, having a place of business at 339 Jefferson Road, Parsippany,

New Jersey 07054. Upon information and belief, Ascend is a wholly owned subsidiary of Alkem and is an agent of Alkem in the United States.

7. On information and belief, Alkem and Ascend are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

8. Upon information and belief, Alkem and Ascend are acting in concert to develop, manufacture, market, and/or distribute generic pharmaceutical products, including the proposed generic version of Spravato® described in ANDA No. 218468, for sale in the state of New Jersey and throughout the United States.

9. On information and belief, Alkem and Ascend hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

10. On information and belief, Alkem and Ascend are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 218468.

11. On information and belief, Alkem, together with its affiliate and/or agent Ascend, prepared and filed the Alkem ANDA No. 218468 that is at issue in this patent infringement suit.

12. On information and belief, Alkem is acting on behalf of itself and on behalf of Ascend with respect to ANDA No. 218468.

## JURISDICTION AND VENUE

13. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**Alkem Laboratories Ltd. ("Alkem")**

16. This Court has personal jurisdiction over Alkem because, *inter alia*, Alkem has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 218468, Alkem will, directly or through its affiliates, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Spravato® brand products in the United States, including in New Jersey, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

17. Exercising personal jurisdiction over Alkem in this District is reasonable given Alkem's contacts in this District and the interest of this District in resolving disputes related to products to be sold herein.

18. This Court also has personal jurisdiction over Alkem because Alkem has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Alkem regularly and continuously transacts business within New Jersey, either directly or through its

affiliates, including by controlling and/or acting through an affiliate (Ascend) incorporated in and having a principal place of business in New Jersey, and by selling pharmaceutical products in New Jersey. On information and belief, Alkem derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

19. On information and belief, Alkem, either directly or indirectly through its agent Ascend, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

20. This Court also has personal jurisdiction over Alkem because, *inter alia*, this action arises from the actions of Alkem directed toward New Jersey. For example, Alkem's counsel sent a letter dated April 18, 2023 to JPI, a corporation with its principal place of business in this Judicial District, stating that Alkem had submitted ANDA No. 218468 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents. If Alkem succeeds in obtaining FDA approval, it would sell its proposed generic versions of JPI's Spravato® brand products in New Jersey and other states, either directly or through its affiliates and/or agents including Ascend, causing injury to Plaintiffs in New Jersey.

21. In the alternative, this Court has personal jurisdiction over Alkem because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

22. Venue in this District is proper for Alkem under 28 U.S.C. §§ 1391(c)(3), including because Alkem is a foreign corporation and is subject to personal jurisdiction in this

District, as alleged herein. On information and belief, Alkem committed acts in preparation of ANDA No. 218468 at the established place of business of Ascend in New Jersey and in connection with the submission of the ANDA from that place of business, either directly or through Ascend. Alkem therefore committed acts of infringement in this District. In addition, as set forth above and on information and belief, Alkem will commit further acts of infringement in this District, continuously transacts business in this District, and has a continuous and permanent presence in this District through its subsidiary, Ascend.

23. Alkem has conceded that venue is proper over Alkem in patent cases in this Judicial District and has consented to, or did not contest the jurisdiction, of this Court in at least the following District of New Jersey actions: *Azurity Pharms., Inc. et al v. Alkem Labs. Ltd.*, Civil Action No. 23-cv-00079 (D.N.J. Jan 6, 2023); *Valeant Pharm. N. Am. LLC v. Alkem Labs. Ltd.*, Civil Action No. 18-cv-13905 (D.N.J. Sept. 14, 2018); *Celgene Corp. v. Alkem Labs. Ltd*., Civil Action No. 18-11265 (D.N.J. June 29, 2018); and *Otsuka Pharm. Co., Ltd. v. Alkem Labs. Ltd. et al*, Civil Action No. 16-cv-06067 (D.N.J. Sept. 26, 2016).

**Ascend Laboratories, LLC ("Ascend")**

24. On information and belief, Ascend, either directly or indirectly through Alkem, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

25. Upon information and belief, Ascend is controlled and/or dominated by Alkem and acts at the direction and for the benefit of Alkem. Alkem describes Ascend as its "primary subsidiary" on its website. *See* https://www.alkemlabs.com/us.php. Ascend states on its website that it originally served as Alkem's "exclusive agent for all its FDA approved drugs,"

and that their partnership "soon developed into the realization that Ascend and Alkem would be better being one company rather than two," resulting in Ascend becoming Alkem's wholly owned subsidiary and supplying "over 100 SKU's" to hospitals, pharmacies and wholesalers in the United States. *See* http://www.ascendlaboratories.com/Home/Background.

26. This Court has personal jurisdiction over Ascend because Ascend is incorporated and maintains its primary place of business in New Jersey. This Court also has personal jurisdiction over Ascend because Ascend is organized and incorporated in New Jersey and has its principal place of business in New Jersey. Additionally, *inter alia*, Ascend has committed an act of patent infringement under 35 U.S.C. §271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 218468, Ascend will, directly or through its affiliates including Alkem, distribute the proposed generic versions of JPI's Spravato® brand products described in ANDA No. 218468 in the United States, including in New Jersey, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents.

27. Exercising personal jurisdiction over Ascend in this District is reasonable given Ascend's contacts in this District and the interest of this District in resolving disputes related to products to be sold herein.

28. This Court also has personal jurisdiction over Ascend because Ascend has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Ascend regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Alkem—including by selling pharmaceutical products in New Jersey. On

information and belief, Ascend derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey .On information and belief, Ascend has substantial, continuous and systematic contacts with New Jersey, maintains its principal place of business in this Judicial District, is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600158194 and is registered as a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003567.

29. On information and belief, Ascend, either directly or indirectly through Alkem, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

30. This Court also has personal jurisdiction over Ascend because, *inter alia*, this action arises from the actions of Ascend directed toward New Jersey, either directly or through Alkem. For example, Alkem's counsel sent a letter dated April 18, 2023 to JPI, a corporation with its principal place of business in this Judicial District, stating that Alkem had submitted ANDA No. 218468 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Spravato® brand products prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents. If Alkem succeeds in obtaining FDA approval, Ascend would sell its proposed generic versions of JPI's Spravato® brand products in New Jersey and other states, either directly or through its affiliates and/or agents including Alkem, causing injury to Plaintiffs in New Jersey.

31. Venue in this District is proper for Ascend under 28 U.S.C. § 1400(b) because Ascend is incorporated under the laws of New Jersey. Venue is also proper for Ascend

because Ascend has a regular and established place of business in this District and, on information and belief, participated in the preparation and submission of ANDA No. 218468 at its established place of business in New Jersey and therefore committed an act of infringement in this District. In addition, on information and belief, Ascend will commit further acts of infringement in this District, as alleged herein.

32. Ascend has conceded that venue is proper over Ascend in patent cases in this Judicial District and has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Otsuka Pharm. Co., Ltd. v. Alkem Labs. Ltd. et al.*, Civil Action No. 1:16-cv-06067 (D.N.J. Sept. 26, 2016); and *AstraZeneca AB et al. v. Alkem Labs. Ltd. et al.*, Civil Action No. 3:15-cv-06609 (D.N.J. Sept. 2, 2015).

**THE PATENTS-IN-SUIT**

33. On December 22, 2020, the ’844 Patent, titled “Methods for the Treatment of Depression” was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the ’844 Patent. A copy of the ’844 Patent is attached as Exhibit A.

34. On November 16, 2021, the ’134 Patent, titled “Methods for the Treatment of Depression” was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the ’134 Patent. A copy of the ’134 Patent is attached as Exhibit B.

35. On April 26, 2022, the ’500 Patent, titled “Methods for the Treatment of Depression” was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the ’500 Patent. A copy of the ’500 Patent is attached as Exhibit C.

36. On September 20, 2022, the ’260 Patent, titled “Pharmaceutical Composition of S-Ketamine Hydrochloride” was duly and legally issued by the United States Patent & Trademark Office. JPNV owns the ’260 Patent. A copy of the ’260 Patent is attached as Exhibit D.

37. JPI holds approved NDA No. 211243 for esketamine nasal spray, which is prescribed and sold under the trademark Spravato®.

38. Pursuant to 21 U.S.C. § 355(b)(1), the '134, '844, '500, and '260 Patents are listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering JPI's Spravato® brand esketamine nasal spray products.

**COUNT I:**
**INFRINGEMENT OF THE '844 PATENT BY DEFENDANTS' ANDA FOR SPRAVATO®**

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. An actual controversy exists between the parties as to whether Defendants' proposed sale of generic esketamine nasal spray products infringes at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent.

41. By letter dated April 18, 2023 ("Alkem Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 218468 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Alkem Notice Letter stated that ANDA No. 218468 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents. ANDA No. 218468 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '844 Patent.

42. ANDA No. 218468 includes a Paragraph IV Certification that the claims of the '844 Patent are invalid, unenforceable, and/or not infringed.

43. Upon information and belief, the Alkem Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

44. The Alkem Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Alkem's Notice Letter.

45. The Alkem Notice Letter purports to include a Notice of Certification for ANDA No. 218468 under 21 C.F.R. § 314.95(c)(6) as to the '844 Patent.

46. Defendants have actual knowledge of the '844 Patent, as shown by the Alkem Notice Letter.

47. On information and belief, Defendants' proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

48. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 218468 seeking approval to manufacture, use, import, offer to sell or sell Defendants' proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '844 Patent. Upon information and belief, the products described in ANDA No. 218468 would infringe, either literally or under the doctrine of equivalents, at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent under 35 U.S.C. § 271(e)(2)(A).

49. On information and belief, physicians and/or patients will directly infringe at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent by use of Defendants' proposed generic versions of Janssen's Spravato® brand products upon approval.

50. On information and belief, upon approval, Defendants will take active steps to encourage the use of Defendants' proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent, for Defendants' pecuniary benefit. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent. Defendants specifically intend their generic esketamine nasal spray products to be used according to their proposed labeling in a manner that infringes at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent. Upon information and belief, Defendants will thus induce the infringement of at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent.

51. On information and belief, if the FDA approves ANDA No. 218468, Defendants will sell or offer to sell their proposed generic products specifically labeled for use in practicing at least one claim of the '844 Patent, wherein Defendants' proposed generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' proposed generic products in accordance with the instructions and/or label provided by Defendants in practicing at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent, and wherein Defendants' generic esketamine nasal spray

products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants' proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-3, 5-8, 11, 13-16, 19-22, 24-26, and 30 of the '844 Patent. On information and belief, Defendants will thus contribute to the infringement of the '844 Patent.

52. On information and belief, the actions described in this Complaint relating to Defendants' ANDA No. 218468 were done by and for the benefit of Defendants.

53. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

54. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT II:**
**INFRINGEMENT OF THE '134 PATENT BY DEFENDANTS' ANDA FOR SPRAVATO®**

55. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

56. An actual controversy exists between the parties as to whether Defendants' proposed sale of generic esketamine nasal spray products infringes at least claims 1-17 and 21-30 of the '134 Patent.

57. By letter dated April 18, 2023, Defendants notified Plaintiffs that they had submitted ANDA No. 218468 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Alkem Notice Letter stated that ANDA No. 218468 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents.

ANDA No. 218468 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '134 Patent.

58. ANDA No. 218468 includes a Paragraph IV Certification that the claims of the '134 Patent are invalid, unenforceable, and/or not infringed.

59. Upon information and belief, the Alkem Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

60. The Alkem Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Alkem's Notice Letter.

61. The Alkem Notice Letter purports to include a Notice of Certification for ANDA No. 218468 under 21 C.F.R. § 314.95(c)(6) as to the '134 Patent.

62. Defendants have actual knowledge of the '134 Patent, as shown by the Alkem Notice Letter.

63. On information and belief, Defendants' proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least claims 1-17 and 21-30 of the '134 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

64. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least claims 1-17 and 21-30 of the '134 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 218468 seeking approval to manufacture, use, import, offer to sell or sell Defendants' proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '134 Patent. Upon information and belief, the products described in

ANDA No. 218468 would infringe, either literally or under the doctrine of equivalents, at least claims 1-17 and 21-30 of the '134 Patent under 35 U.S.C. § 271(e)(2)(A).

65. On information and belief, physicians and/or patients will directly infringe at least claims 1-17 and 21-30 of the '134 Patent by use of Defendants' proposed generic versions of Janssen's Spravato® brand products upon approval.

66. On information and belief, upon approval, Defendants will take active steps to encourage the use of Defendants' proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-17 and 21-30 of the '134 Patent, for Defendants' pecuniary benefit. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-17 and 21-30 of the '134 Patent. Defendants specifically intend their generic esketamine nasal spray products to be used according to their proposed labeling in a manner that infringes at least claims 1-17 and 21-30 of the '134 Patent. Upon information and belief, Defendants will thus induce the infringement of at least claims 1-17 and 21-30 of the '134 Patent.

67. On information and belief, if the FDA approves ANDA No. 218468, Defendants will sell or offer to sell their proposed generic products specifically labeled for use in practicing at least one claim of the '134 Patent, wherein Defendants' proposed generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' proposed generic products in accordance with the instructions and/or label provided by Defendants in practicing at least claims 1-17 and 21-30 of

the ’134 Patent, and wherein Defendants’ generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants’ proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-17 and 21-30 of the ’134 Patent. On information and belief, Defendants will thus contribute to the infringement of the ’134 Patent.

68. On information and belief, the actions described in this Complaint relating to Defendants’ ANDA No. 218468 were done by and for the benefit of Defendants.

69. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

70. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

**COUNT III:**
**INFRINGEMENT OF THE ’500 PATENT BY DEFENDANTS’ ANDA FOR SPRAVATO®**

71. Plaintiffs re-allege paragraphs 1-36 as if fully set forth herein.

72. An actual controversy exists between the parties as to whether Defendants’ proposed sale of generic esketamine nasal spray products infringes at least claims 1-5, 8-9, 12-16, and 19-20 of the ’500 Patent.

73. By letter dated April 18, 2023, Defendants notified Plaintiffs that they had submitted ANDA No. 218468 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Alkem Notice Letter stated that ANDA No. 218468 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic esketamine nasal spray products prior to the expiration of certain Orange Book listed patents.

ANDA No. 218468 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '500 Patent.

74. ANDA No. 218468 includes a Paragraph IV Certification that the claims of the '500 Patent are invalid, unenforceable, and/or not infringed.

75. Upon information and belief, the Alkem Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

76. The Alkem Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Alkem's Notice Letter.

77. The Alkem Notice Letter purports to include a Notice of Certification for ANDA No. 218468 under 21 C.F.R. § 314.95(c)(6) as to the '500 Patent.

78. Defendants have actual knowledge of the '500 Patent, as shown by the Alkem Notice Letter.

79. On information and belief, Defendants' proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

80. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 218468 seeking approval to manufacture, use, import, offer to sell or sell Defendants' proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '500 Patent. Upon information and belief, the products

described in ANDA No. 218468 would infringe, either literally or under the doctrine of equivalents, at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent under 35 U.S.C. § 271(e)(2)(A).

81. On information and belief, physicians and/or patients will directly infringe at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent by use of Defendants' proposed generic versions of Janssen's Spravato® brand products upon approval.

82. On information and belief, upon approval, Defendants will take active steps to encourage the use of Defendants' proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent, for Defendants' pecuniary benefit. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent. Defendants specifically intend their generic esketamine nasal spray products to be used according to their proposed labeling in a manner that infringes at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent. Upon information and belief, Defendants will thus induce the infringement of at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent.

83. On information and belief, if the FDA approves ANDA No. 218468, Defendants will sell or offer to sell their proposed generic products specifically labeled for use in practicing at least one claim of the '500 Patent, wherein Defendants' proposed generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' proposed generic products in accordance with the

instructions and/or label provided by Defendants in practicing at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent, and wherein Defendants' generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants' proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-5, 8-9, 12-16, and 19-20 of the '500 Patent. On information and belief, Defendants will thus contribute to the infringement of the '500 Patent.

84. On information and belief, the actions described in this Complaint relating to Defendants' ANDA No. 218468 were done by and for the benefit of Defendants.

85. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

86. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT IV:**
**INFRINGEMENT OF THE '260 PATENT BY DEFENDANTS' ANDA FOR SPRAVATO®**

87. Plaintiffs re-allege paragraphs 1-36 as if fully set forth herein.

88. An actual controversy exists between the parties as to whether Defendants' proposed sale of generic esketamine nasal spray products infringes at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent.

89. By letter dated April 18, 2023, Defendants notified Plaintiffs that they had submitted ANDA No. 218468 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Alkem Notice Letter stated that ANDA No. 218468 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic

esketamine nasal spray products prior to the expiration of certain Orange Book listed patents. ANDA No. 218468 specifically seeks FDA approval to market generic versions of JPI's Spravato® brand esketamine nasal spray products in one or more doses prior to the expiration of the '260 Patent.

90. ANDA No. 218468 includes a Paragraph IV Certification that the claims of the '260 Patent are invalid, unenforceable, and/or not infringed.

91. Upon information and belief, the Alkem Notice Letter was sent to Plaintiffs via overnight mail no earlier than April 18, 2023.

92. The Alkem Notice Letter was subsequently received by Plaintiffs, and Plaintiffs are commencing this action within 45 days of the date of receipt of Alkem's Notice Letter.

93. The Alkem Notice Letter purports to include a Notice of Certification for ANDA No. 218468 under 21 C.F.R. § 314.95(c)(6) as to the '260 Patent. The Alkem Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '260 Patent.

94. Defendants have actual knowledge of the '260 Patent, as shown by the Alkem Notice Letter.

95. On information and belief, Defendants' proposed generic versions of JPI's Spravato® brand products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

96. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the

'260 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 218468 seeking approval to manufacture, use, import, offer to sell or sell Defendants' proposed generic versions of Janssen's Spravato® brand products before the expiration date of the '260 Patent. Upon information and belief, the products described in ANDA No. 218468 would infringe, either literally or under the doctrine of equivalents, at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent under 35 U.S.C. § 271(e)(2)(A).

97. On information and belief, physicians and/or patients will directly infringe at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent by use of Defendants' proposed generic versions of Janssen's Spravato® brand products upon approval.

98. On information and belief, upon approval, Defendants will take active steps to encourage the use of Defendants' proposed generic versions of Janssen's Spravato® brand products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients in a manner that infringes at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent, for Defendants' pecuniary benefit. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Spravato® labeling, with limited exceptions. The use of Spravato® according to its approved labeling meets the elements of at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent. Defendants specifically intend their generic esketamine nasal spray products to be used according to their proposed labeling in a manner that infringes at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent. Upon information and belief, Defendants will thus induce the infringement of at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent.

99. On information and belief, if the FDA approves ANDA No. 218468, Defendants will sell or offer to sell their proposed generic products specifically labeled for use in practicing at least one claim of the '260 Patent, wherein Defendants' proposed generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' proposed generic products in accordance with the instructions and/or label provided by Defendants in practicing at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent, and wherein Defendants' generic esketamine nasal spray products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants' proposed generic esketamine nasal spray products are specifically designed for use in a manner that infringes at least claims 1-2, 6-19, 22, 25-26, 31-42, 46-58, 61, 64-65, and 70-75 of the '260 Patent. On information and belief, Defendants will thus contribute to the infringement of the '260 Patent.

100. On information and belief, the actions described in this Complaint relating to Defendants' ANDA No. 218468 were done by and for the benefit of Defendants.

101. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

102. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully pray for the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '844, '134, '500, and '260 Patents through Defendants' submission of ANDA No. 218468 to the FDA to obtain approval to manufacture, use, import,

offer to sell, and sell Defendants' proposed generic versions of JPI's Spravato® brand products identified in this Complaint in the United States before the latest of the expiration dates of the '844, '134, '500, and '260 Patents;

B. Enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Defendants' commercial manufacture use, offer for sale, or sale within the United States, or importation into the United States of Defendants' proposed generic versions of JPI's Spravato® brand products identified in this Complaint, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents, constitutes infringement of one or more claims of the '844, '134, '500, and '260 Patents under 35 U.S.C. § 271(a), (b), or (c);

C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 218468 be a date that is not earlier than the latest of the expiration dates of the '844, '134, '500, and '260 Patents, or such later date as the Court may determine;

D. Order that Defendants, their affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Defendants, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Defendants' proposed generic versions of JPI's Spravato® brand products identified in this Complaint, and any other product that infringes or contributes to the infringement of the '844, '134, '500, and '260 Patents, prior to the latest of the expiration dates of the '844, '134, '500, and '260 Patents, or such later date as the Court may determine;

E. If Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Spravato® brand products identified in this Complaint prior to the latest of the expiration dates

of the ’844, ’134, ’500, and ’260 Patents, a Judgment awarding damages to Plaintiffs resulting from such infringement with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorneys’ fees; and

G. Award such further and other relief that the Court deems proper and just.

Dated: May 30, 2023

*s/ Keith J. Miller*
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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 30, 2023

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